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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,210	07/08/2003	Michael S. Kopreski	00-1313-D	9776

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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/616,210

Applicant(s)

KOPRESKI ET AL.

Examiner

Frank W. Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 3-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III, claims 18-28 in the reply filed on October 21, 2005 is acknowledged. The traversal is on the ground(s) that "[A]pplicants traverse restriction of claims 3-17 and 18-28 into Groups II and III in the instant Action. As set forth in the Action itself, these claims are both classified in class 435, subclass 91.51. Applicants respectfully submit that search and examination of all claims designated as belonging in Groups II and III in the Action would exert no undue hardship on the Office, since a search in the relevant classification area would necessarily identify any art relevant to the patentability of claims 3-28".

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such Groups II and III will be examined. First, the restriction is not based on the classification of Groups II and III but is based on that different and distinct searches are required for Groups II and III. For example, the search required for Group II such as 5T4 directed therapy in claim 15 is not required for Group III while the search required for Group III such as placenta in claim 24 is not required for Group II. Second, applicant has no evidence to show that a search in the relevant classification area would necessarily identify any art relevant to the patentability of claims 3-28. Therefore, the requirement is still deemed proper and is therefore made FINAL.

2. Based on the amendments filed on October 21, 2005, specifically on the amendment on claim 18, restriction to one of the following inventions is required under 35 U.S.C. 121:

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II. Claims 3-20, drawn to a method of detecting 5T4 RNA in blood plasma or serum in blood plasma or serum from a human (claims 3, 5, 6, and 12-14) and a method of detecting 5T4 RNA in a bodily fluid from a human (claims 4-6 and 12-14), a method of identifying a human having 5T4 expressing cells or tissue (claims 7-11), a method for selecting a human with cancer for a 5T4 directed therapy (claims 15-17), and a method of detecting 5T4 RNA in blood plasma or serum from a woman for detecting, monitoring, or evaluating trophoblast tissue (claims 18-20), classified in class 435, subclass 91.51.

III. Claims 21-35, drawn to, a method of detecting trophoblast tissue in a woman post-partum or with an antecedent pregnancy (claims 21-23), a method of monitoring the placenta during a pregnancy (claims 24-29), a method of detecting 5T4 RNA in a bodily fluid from a pregnant or post-partum woman for detecting, diagnosing, monitoring or evaluating a placental disease or condition (claims 30-33), and a method of detecting trophoblast RNA in a blood plasma or serum from a woman for detecting, diagnosing, monitoring or evaluating a placental tissue (claims 34-36), classified in class 435, subclass 91.51.

3. The inventions are distinct, each from the other because of the following reasons:

Groups II and III are distinct and independent inventions in that they are directed to different methods which have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as 5T4 directed therapy in claim 15 is not required for Group

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III while the search required for Group III such as placenta in claim 24 is not required for Group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Frank Lu
Primary Examiner
January 6, 2006

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned to the right of the typed name.